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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,690	07/27/2005	Brid Delvin	049135-5004-US	7308

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/527,690

Applicant(s)

DELVIN ET AL

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-15, 22, 23, 25, 26, 29, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 8-15, 22, 23, 25, 26, 29, 38, 39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to preliminary amendment, claims 6, 7, 16-21, 24, 27, 28, 30-37, 40-52 have been cancelled. Claims 1-5, 8-15, 22, 23, 25, 26, 29, 38, 39 are pending.



The following abbreviations are used hereinbelow:

SCM = synthetic cervical mucus

SVF = synthetic vaginal fluid

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I) Claims 1-5, 8-14, 29, 38, 39, drawn to a method for delivering a therapeutic agent to a patient.

II) Claims 15, 22, 23, 25, 26, drawn to a method for treating or preventing a disease

The claimed inventions are distinct. A person might want to use the formulation (to which the claims are directed) solely for lubrication purposes. That formulation might contain a compound which qualifies not only as a preservative but as a "therapeutic agent". In addition, other compounds might serve dual roles. For example, there may be assertions in the patent literature that glycerol exhibits some sort of pharmacological activity, at least *in vitro*. Even sodium chloride could qualify as a "therapeutic

agent", at least for the patient who is hypotonic or even hypertensive. However, in the event that Group I is elected, and claims therein found allowable, it is likely that novelty would accrue to the Group II claims (provided also that whatever limitations had been introduced into the Group I claims were also introduced into the Group II claims).

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is chosen for initial examination, election of the following is required:

- a) a specific mucosa with which the formulation is contacted (e.g., vaginal or rectal);
- b) a specific therapeutic agent that is present in the formulation;
- c) the contents of a specific composition in which 100% of the contents are accounted for;
- d) one of the following: (i) the composition is a SCM, or (ii) the composition is a SVF, or (iii) the composition is a combination of a SCM and a SVF;
- e) in the event that the composition is or contains a SFV, election of one of the following is

required: (i) the SFV has two and only two properties of the composition that is recited in claim 8, or (ii) the SFV has three properties of the composition that is recited in claim 8;

f) in the event that the composition is or contains a SFV, and in the further event that the SFV has two and only two properties of the composition that is recited in claim 8, which two properties are they?

g) in the event that the composition is a SCM, what is the viscosity of the SCM...?

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In the event that Group II is chosen for initial examination, election of the following is required:

a) a specific mucosa with which the formulation is contacted (e.g., vaginal or rectal);

b) a specific therapeutic agent that is present in the formulation;

c) the contents of a specific composition in which 100% of the contents are accounted for;

d) one of the following: (i) the composition is a SCM, or (ii) the composition is a SVF, or (iii) the composition is a combination of a SCM and a SVF;

e) in the event that the composition is or contains a SFV, election of one of the following is required: (i) the SFV has two and only two properties of the composition that is recited in claim 8, or (ii) the SFV has three properties of the composition that is recited in claim 8;

f) in the event that the composition is or contains a SFV, and in the further event that the SFV has two and only two properties of the composition that is recited in claim 8, which two properties are they?

g) in the event that the composition is a SCM, what is the viscosity of the SCM...?

h) a specific disease which is to be treated or prevented.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "D. Lukton", located below the contact information.

**DAVID LUKTON
PATENT EXAMINER
GROUP 1800**